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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,126	04/16/2001	Randolph J. Noelle	P 0280602 1999-30-0522C1	4674

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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	12

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/835126	NOELLE
	Examiner	Art Unit
	GAMBEL	1644

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 9/24/02; 11/30/02

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) _____ is/are pending in the application. 1-11

4a) Of the above claim(s) _____ is/are withdrawn from consideration. 12

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) _____ is/are rejected. 1-11

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☑ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

PAPER NO. 12

DETAILED ACTION

1. Applicant's election alloantigen bearing cells as the type of cells; anti-CD40 ligand (anti-gp39) antibodies as the gp39 antagonist; and transplantation as the disease in Paper Nos. 8 and 11, filed 9/24/02 and 2/28/03, is acknowledged.

Claims 1-11 are being acted upon as the elected invention

Claim 12 has been withdrawn as being drawn to the non-elected species.

For examination purposes, the claims are read in light of the elected invention with respect to anti-CD40 ligand (anti-gp39) antibodies as the gp39 antagonist

2. Applicant should amend the first line of the specification to update the status of the priority document.

3. Formal drawings, filed 11/13/01, comply with 37 CFR 1.84.

4. The Abstract of the Disclosure is objected to because it does not adequately describe the claimed invention. Correction is required. See MPEP 608.01(b).

5. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate corrections are required

6. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 C.F.R. § 1.75(d)(1) and M.P.E.P. § 608.01(l). Correction would be required.

There appears insufficient written description is provided for the recitation of "one to thirty days" and "from 5 - 15 days" as it applies to any gp39-/CD40L-specific antagonist (e.g. see claims 6-7).

If there is written support for the recitation of "one to thirty days" and "from 5 - 15 days" as it applies to any gp39-/CD40L-specific antagonist (e.g. see claims 6-7) in the specification as filed, then applicant should provide such support.

7. Claim 9 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is indefinite in that there is an ambiguity as which T cells (donor or recipient) are being depleted.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-8 and 10-11 are rejected under 35 U.S.C. § 102(e) as being anticipated by Noelle et al. (U.S. Patent No. 5,876,718) (see entire document).

Noelle et al. teach inducing T cell non-responsiveness to desired alloantigens with gp39 antagonists, including the use of anti-CD40 ligand (anti-gp39) antibodies (gp39 Antagonists) and antigen presenting cells, including bone marrow and peripheral bloods cells (Cells of Induction of Antigen-Specific Tolerance), for transplantation, including bone marrow transplantation, including before transfer to the transplant recipient in vitro (Administration of Cells and gp39 Antagonists) (see entire document, including Detailed Description of the Invention). Although Noelle et al. does not mention mixed lymphocyte reaction per se, it would have readily apparent to the one of ordinary skill in the art at the time the invention was made that a mixed lymphocyte reaction was accomplished by carrying out the above-mentioned procedures. Although Noelle et al. is silent about the particular time ranges recited in the instant claims 6-7 per se, one of ordinary skill would have immediately envisaged at the time the invention was made that the culture of donor T cells would have fallen into such ranges (e.g. 1, 3, 5 days), as known typical days of culturing T cells at the time the invention was made, including the Examples set forth in Noelle et al. Antigen presenting cells are depleted of T cells (see columns 10, paragraph 2). Transplantation including bone marrow transplantation are provided to recipients in need of immune reconstitution as a result of disease or disease treatment. Applicant is reminded that no more of the reference is required that it sets forth the substance of the inventions. The claimed functional limitations would be inherent properties of the referenced methods.

11. Claims 1-3 and 6-11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Noelle et al. (U.S. Patent No. 5,876,718) in view of the art known use of irradiating antigen presenting cells at the time the invention was made, as evidenced by Rooney et al. (U.S. Patent No. 5,962,318) and in view of the art known culturing of donor T cells for treatments over varying lengths of time, as evidenced by Riddell et al. (J. Immunol. Methods 128: 189-201).

Noelle et al. teach inducing T cell non-responsiveness to desired alloantigens with gp39 antagonists, including the use of anti-CD40 ligand (anti-gp39) antibodies (gp39 Antagonists) and antigen presenting cells, including bone marrow and peripheral bloods cells (Cells of Induction of Antigen-Specific Tolerance), for transplantation, including bone marrow transplantation, including before transfer to the transplant recipient in vitro (Administration of Cells and gp39 Antagonists) (see entire document, including Detailed Description of the Invention). Although Noelle et al. does not mention mixed lymphocyte reaction per se, it would have readily apparent to the one of ordinary skill in the art at the time the invention was made that a mixed lymphocyte reaction was accomplished by carrying out the above-mentioned procedures. Transplantation including bone marrow transplantation are provided to recipients in need of immune reconstitution as a result of disease or disease treatment.

Although Noelle et al. is silent about the particular time ranges set recited in the instant claims 6-7 per se, one of ordinary skill would have immediately envisaged at the time the invention was made that the culture of donor T cells would have fallen into such ranges (e.g. 1, 3, 5 days), as known typical days of culturing T cells at the time the invention was made, including the Examples set forth in Noelle et al.

In addition, Riddell et al. teach the growth and expansion of antigen-specific T cells in culture for up to three months that can be employed for therapeutic use (see entire document).

Given the desired endpoint of nonresponsiveness, the ordinary artisan would have expected to culture the donor T cells, antigen presenting cells with gp39 antagonists for various times, including those encompassed by the claimed invention to achieve the desired endpoint.

It is noted that Noelle et al. teach depleting antigen presenting cells of T cells (see column 10, paragraph 2). In addition, antigen presenting cells for a variety of immunological processes were routinely irradiated at the time the invention was made to alleviate the activity of other cell types including T cells given that antigen presentation was still provided, as evidenced by Rooney et al. (e.g. see columns 14-15, overlapping paragraph and Examples 1-3 in columns 20-36).

One of ordinary skill in the art at the time the invention was made would have been motivated to culture donor T cells in vitro under certain conditions and times encompassed by the claimed limitations with a gp39 / CD40 ligand antagonist such as anti-CD40 ligand (anti-gp39) antibodies induce antigen-specific unresponsiveness in the donor T cells populations prior to transplantation for treating various human conditions and diseases. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

One of ordinary skill in the art at the time the invention was made would have been motivated to culture donor T cells in vitro under certain conditions and times encompassed by the claimed limitations with a gp39 / CD40 ligand antagonist such as soluble CD40 to induce antigen-specific unresponsiveness in the donor T cells populations prior to transplantation for treating various human conditions and diseases. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

13. Claims 1-3, (4-5), 6-11 (and 12) are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-3, (4-5), 6-11 (and 12) of copending application Serial No. 09/835,126. This is a *provisional* double patenting rejection since the conflicting claims have not in fact been patented.

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

PHILLIP GAMBEL

Phillip Gambel, PhD.
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Technology Center 1600
May 19, 2003